EC-2000-007
IV-D-154

The Dow Chemical Company
Midland, Michigan 48674

2030 Dow Center

February 26, 2002

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center (Mail Code 2201A)
Attn: Docket No. EC-2000-007
4th Floor, Room 4033
1200 Pennsylvania Avenue, NW
Washington, DC 20004

Re: Comments of The Dow Chemical Company on EPA's Proposed Rule on Establishment of Electronic Reporting; Electronic Records

Dear Sir or Madam:

Attached for filing in this docket are an original and three copies of the comments of The Dow Chemical Company on the proposed Cross-Media Electronic Reporting and Recordkeeping Rule, together with attachments.

Sincerely,

Mark Duvall

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Attachments

Before the U.S. Environmental Protection Agency

Establishment of Electronic Reporting; Electronic Records; Proposed Rule

(Docket No. EC-2000-007)

66 Fed. Reg. 46162 (Aug. 31, 2001)

Comments of

The Dow Chemical Company

February 26, 2002

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INTRODUCTION

The Dow Chemical Company ("Dow") is pleased to have the opportunity to submit its comments on the proposed Cross-Media Electronic Reporting and Recordkeeping Rule ("CROMERRR").[1] EPA extended the comment deadline until February 27, 2002.[2]

Dow is a global manufacturer of chemicals and plastics with many facilities in the United States that are subject to EPA reporting and recordkeeping requirements. Dow has previously submitted comments in this docket.[3] These comments supplement those earlier comments, which should also be consulted.

EXECUTIVE SUMMARY

EPA should withdraw the electronic recordkeeping provisions of CROMERRR, conduct appropriate analyses, consult with regulated facilities, and only then, if appropriate, re-propose them.

These comments discuss the following ten reasons why EPA should withdraw the recordkeeping provisions of CROMERRR:

1. EPA presented the recordkeeping provisions as voluntary in nature. It indicated that regulated facilities could choose whether or not to comply. The record now shows, however, that the recordkeeping provisions would not be voluntary in any meaningful sense. It is impossible for most regulated facilities to comply with EPA recordkeeping requirements without using electronic recordkeeping. Thus, the recordkeeping provisions would be mandatory in effect.

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[1] 66 Fed. Reg. 46162 (Aug. 31, 2001).

[2] 66 Fed. Reg. 59392 (Nov. 28, 2001) (extending the deadline to Jan. 28, 2002); 67 Fed. Reg. 278 (Jan. 3, 2002) (further extending the deadline to Feb. 27, 2002).

[3] Dow's previous comments in this docket include the following:

- Item IV-D-007 (Dow comments to OMB and EPA on the Paperwork Reduction Act implications of CROMERRR dated October 8, 2001).
- Item IV-F-001 (transcript of the October 29, 2001 public hearing in Washington, DC, comments by Mark Duvall), pp. 38-49, 97-99.
- Item IV-F-003 (transcript of the November 9, 2001 public hearing in Chicago, comments by David Keyes), pp. 59-69, 71, 102-03.
- Item number unavailable: transcript of the January 17, 2001 public hearing in Washington, DC, comments by Mark Duvall.
- Item number unavailable: transcript of the January 31, 2001 public hearing in Dallas, Texas, comments by Nancy Freshour.
- Item number unavailable: Written Dow presentation submitted at the October 29, 2001 public hearing by Mark Duvall.
- Item number unavailable: Written Dow presentation submitted at the November 9, 2001 public hearing by David Keyes.
- Item number unavailable: Written Dow presentation submitted at the January 17, 2002 public hearing by Mark Duvall.
- Item number unavailable: Written Dow presentation submitted at the January 31, 2002 public hearing by Nancy Freshour.

2. EPA predicted that the recordkeeping provisions would affect only a handful of regulated facilities, some 428 per year. Because the recordkeeping provisions would be mandatory in effect, almost every facility subject to EPA recordkeeping requirements, some 1.2 million facilities or more, would have to comply with the recordkeeping provisions.

3. The costs of the recordkeeping provisions would be prohibitive. EPA estimated that the initial cost of complying with the recordkeeping provisions would be about $40,000, and the annual costs would be about $17,000. Using these estimates, the initial cost for 1.2 million regulated facilities would be about $48 billion, and the annual cost would be about $20 billion. These costs would make the recordkeeping provisions the most expensive in EPA history. EPA's estimates are extremely low, however; EPA describes them as for a "low-end" system. Dow estimates that the implementation cost would be over a million dollars per facility. Experience under FDA's counterpart to CROMERRR, 21 CFR Part 11, has shown that large pharmaceutical companies are spending more than $100 million apiece for compliance. Thus, the actual costs of the recordkeeping provisions would be truly staggering. A substantial component of the costs would be the audit trail requirement, as almost no software available for most applications has that capability. Another significant component would be CROMERRR's searchability requirement; again, much software does not offer that functionality. Even if a vendor were to offer software claiming to provide an audit trail and searchability, the regulated facility would have to license, validate, install, and train on the new software, as well as integrate it with connected systems, at a huge cost. These requirements would also put U.S. laboratories at a competitive disadvantage with foreign laboratories not subject to these expensive requirements.

4. The electronic archiving requirement would be technologically infeasible. It is not practical to maintain legacy hardware and software for extended periods solely to maintain electronic records for potential EPA inspection. The alternative is migrating electronic records from one version of software and hardware to another, repeatedly, for the entire record retention period, which in some cases could last decades. To date no one has figured out how to migrate electronic records without data loss, yet the archiving requirement would prohibit any data loss. This is a problem that the federal government has been wrestling with for several years, without success. EPA should not require 1.2 million or more regulated facilities to achieve what the federal government has been unable to accomplish—learn how to maintain electronic records for extended periods without data loss.

5. EPA asserted that the recordkeeping provisions are supported in part by the Government Paperwork Elimination Act ("GPEA"). The GPEA requires EPA to make electronic recordkeeping available to regulated facilities as an option. EPA has already done that. For some recordkeeping requirements it explicitly allows

electronic recordkeeping. Most other recordkeeping requirements are media-neutral, so that they implicitly allow electronic recordkeeping. To meet the GPEA, at most EPA would have to remove any obstacles to electronic recordkeeping (e.g., a requirement for a handwritten signature). The GPEA does not in any way support the anti-fraud provisions of CROMERRR.

6. The GPEA actually prohibits EPA from adopting the anti-fraud provisions. First, the provisions would treat electronic records less favorably than paper records. The audit trail and searchability requirements go far beyond what EPA requires of paper records. It is this less favorable treatment of electronic records that caused EPA to acknowledge that only 428 regulated facilities per year would choose to comply with the recordkeeping provisions. Second, contrary to the aim of the GPEA in amending the Paperwork Reduction Act, the anti-fraud provisions would increase rather than decrease paperwork burdens. Third, they would subject regulated facilities to additional regulation because they would not be voluntary.

7. EPA's primary justification for the recordkeeping provisions is an asserted need to deter and detect fraud in electronic recordkeeping. EPA has put nothing into the record of this proceeding to indicate that fraud in electronic recordkeeping is even an issue. While both OMB and the Justice Department directed EPA to conduct analyses of the risks of fraud and the costs and benefits of different ways to control those risks, EPA performed no such analyses. Instead, it chose a "one-size-fits-all" approach that equates the risk of fraud in all program areas, in all applications, and requires a "Cadillac" set of controls to deter and detect fraud. All federal agencies are subject to the GPEA, but not one of them (other than FDA, prior to adoption of the GPEA) has chosen to take EPA's approach. The suggestion that laboratory fraud cases justifies the recordkeeping provisions fails because nothing in the record discusses laboratory fraud. Any lab fraud cases that may have occurred are EPA successes accomplished without the CROMERRR safeguards being in place. Additionally, EPA has shown no connection between potential fraud in laboratories and fraud in any other program area. Ironically, EPA's assertion that CROMERRR's provisions are necessary to establish the reliability of electronic records could backfire, making it harder in other contexts for enforcement agencies to prove that electronic records lacking those provisions are reliable. Moreover, experience has shown that courts are receptive to the admission of electronic records, in that they are generally considered reliable. Thus, EPA's premise that audit trails and searchability functions are necessary to establish reliability has been disproved in court.

8. EPA has proposed that electronic recordkeeping could not begin until such time, and in such program areas, as EPA may announce from time to time. This provision would throw almost all regulated facilities into non-compliance upon the effective date of CROMERRR. Electronic recordkeeping is a fact of life. It is pervasive. Regulated facilities cannot comply without it. The regulated community cannot wait for EPA to give permission to keep electronic records.

9. EPA has not met a variety of procedural requirements applicable to this rulemaking. Contrary to the Administrative Procedure Act, the proposed rule's preamble failed to give adequate notice of what EPA was proposing, as it referred to the recordkeeping provisions as voluntary. Accordingly, many regulated facilities may have lost their opportunity to comment on what would in practice prove to be a mandatory, intrusive, and very burdensome regulation. Contrary to the Paperwork Reduction Act, EPA's Information Collection Request did not provide an "objectively supported estimate" of the paperwork burden. By suggesting that only 428 regulated facilities would be affected by the rule annually, at a cost of a few tens of thousands of dollars, EPA has not presented OMB or the public with realistic estimates, thus handicapping their ability to comment on the paperwork burden. Contrary to the Regulatory Flexibility Act, EPA did not prepare an analysis of the impact of the rule on small businesses. EPA justified this decision by asserting that there would be no significant impact, although most small businesses would be affected and the impact on them would be very substantial. Contrary to the Unfunded Mandates Reform Act, EPA did not prepare an analysis of the costs and benefits of the proposal on the private sector and government. The costs would exceed $100 million per year, the threshold for triggering this requirement.

10. EPA should withdraw the recordkeeping provisions before revising them. It has time to do so, as the GPEA does not mandate the recordkeeping provisions. EPA needs to make fundamental changes, conduct extensive analyses, and gather additional information. It should consult with regulated facilities on particular alternatives. It needs to design an approach that is not "one-size-fits-all", but rather addresses particular risks of fraud with appropriate controls responsive to the nature and magnitude of the risks. It needs to give the public adequate notice of what it intends to promulgate, so as to provide an opportunity for comment. It cannot do any of these without first withdrawing the proposal.

In conclusion, EPA should not adopt recordkeeping provisions at this time. Instead, it should withdraw the recordkeeping provisions for further consideration.

DISCUSSION

1. The Recordkeeping Provisions Would Not Be Voluntary.

A central assumption of the recordkeeping provisions is that they would be voluntary:

> Under today's proposal, electronic document submission or electronic recordkeeping will be totally voluntary.[4]

[4] 66 Fed. Reg. at 46162.

> For regulated entities that choose to keep records electronically, today's proposal requires the adoption of best practices for electronic records management.[5]
>
> Further, electronic reporting and recordkeeping would be voluntary and would likely be used by facilities only if cost-effective and non-duplicative with their other compliance activities.[6]

These statements mirror those FDA used in adopting its counterpart to CROMERRR in 1997, 21 CFR Part 11.[7] Just as Part 11 has proven to be mandatory in practice, and tremendously expensive, so the CROMERRR recordkeeping provisions would be mandatory and very costly.

From this assumption of voluntariness flowed many erroneous EPA decisions on CROMERRR, including the following:

- The number of facilities affected: "However, it was also assumed that a very low number of facilities (0.5 percent) of the current regulated entities, would elect to acquire new electronic recordkeeping systems to implement the CROMERRR recordkeeping option."[8]
- The relevance of having costs exceed benefits: "[F]acilities may not find it cost-effective to develop an electronic records system unless it addresses both EPA and non-EPA business purposes."[9]
- The idea that EPA can tell regulated entities when they may begin to keep records electronically: "Any regulated company or other entity that maintains records addressed by today's proposal . . . under EPA regulations can store them in an electronic form subject to the proposed criteria for electronic recordkeeping as soon as EPA announces that the specified records may be kept electronically.[10]
- Application of the Regulatory Flexibility Act: "Today's rule is not subject to the RFA because electronic reporting and recordkeeping is voluntary . . . ."[11]

However, as EPA has come to understand, the recordkeeping provisions would not be voluntary in any meaningful sense; rather, in effect they would be mandatory. Accordingly, decisions based on the understanding that the recordkeeping provisions would be voluntary are flawed.

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[5] 66 Fed. Reg. at 46164.

[6] EPA, "Supporting Statement for Information Collection Request 2002.02, 'Electronic Reporting and Recordkeeping—Proposed Rule'" (2001), available at www.epa.gov/icr (Attachment 1) ("CROMERRR ICR") at 13.

[7] For example, FDA claimed: "The activities regulated by this rule are voluntary; no entity is required by this rule to maintain or submit records electronically if it does not wish to do so. Presumably, no firm (or other regulated entity) will implement electronic recordkeeping unless the benefits to that firm are expected to exceed any costs (including capital and maintenance costs). Thus, the industry will incur no net costs as a result of this rule." 62 Fed. Reg. 13430, 13462 (Mar. 20, 1997).

[8] 66 Fed. Reg. at 46178.

[9] 66 Fed. Reg. at 46178.

[10] 66 Fed. Reg. at 46167. See proposed 40 CFR § 3.2(b)(2), 66 Fed. Reg. at 46189.

[11] 66 Fed. Reg. at 46186.

The mandatory nature of the recordkeeping provisions flows directly from the proposed definition of the key term, "electronic record":

> *Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.[12]

The word "or" clarifies that any of the listed actions would be sufficient to make digital information be classified as an electronic record. The implications of this definition include the following:

- Printing out electronic records would not affect their continued status as electronic records, since they would have been "created" or "maintained" at some point in their existence.[13]
- Even a word processing document, printed out and treated thereafter as an ordinary paper document, would be considered an electronic record, because the document would have been "created" electronically.[14]
- The recordkeeping provisions would not be limited to final versions of documents, but would also apply to "data" and "other information" even if preliminary in nature or if never organized into a "final" form.

The bottom line is that any use of a computer to keep records required by EPA recordkeeping requirements would be enough to trigger the CROMERRR electronic records provisions. Numerous commenters have pointed this out to EPA.

Furthermore, the record now establishes that it is impossible to comply with many EPA recordkeeping requirements without the use of computers. EPA specifically solicited comments on current electronic recordkeeping practices.[15] In response, at the public hearings on January 17 and January 31, 2002, and in written comments, many regulated entities reported that electronic recordkeeping is pervasive and they have no alternative but to use computers to meet EPA recordkeeping requirements.[16] Small facilities as well as larger ones are dependent on computers to comply with EPA requirements to keep records. Such digital data would be, by definition, electronic records triggering the full panoply of CROMERRR's recordkeeping requirements.

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[12] Proposed 40 CFR § 3.3, 66 Fed. Reg. at 46189. This is almost identical to the definition of "electronic record" in 21 CFR § 11.3(b)(6).

[13] Similarly, Part 11 applies to "systems that create and maintain electronic records . . . , even though some of those electronic records may be printed on paper at certain times." 62 Fed. Reg. at 13437, comment 22.

[14] Thus, the CROMERRR recordkeeping provisions lack even the "typewriter" exception that FDA adopted in its version of CROMERRR, 21 CFR Part 11. See 62 Fed. Reg. at 13437, comment 22 ("Part 11 is not intended to apply to computer systems that are merely incidental to the creation of paper records that are subsequently maintained in traditional paper-based systems. In such cases, the computer systems would function essentially like manual typewriters or pens and any signatures would be traditional handwritten signatures.").

[15] 67 Fed. Reg. 278, 279 (Jan. 3, 2002).

[16] See in particular Dow's written comments submitted at the January 17 and January 31 public hearings.

As a consequence, the "choice" to keep records electronically is illusory. There is no choice. Regulated facilities cannot go back to using only fountain pens, pencils, adding machines, and manual typewriters. They must use computers to operate in today's advanced technological environment. In doing so, they would be subject to the CROMERRR recordkeeping provisions. Those provisions cannot be classified as anything other than mandatory.[17]

2. The Recordkeeping Provisions Would Apply to Over a Million Regulated Facilities.

EPA estimated that "a very low number (0.5 percent) of the current regulated entities, would elect" to comply with the CROMERRR recordkeeping provisions.[18] EPA's Information Collection Request states:

> EPA estimates that, on average, 428 facilities will acquire and install electronic recordkeeping systems annually.[19]

As shown above, however, the recordkeeping provisions would not be voluntary and would apply on a mandatory basis to virtually all regulated entities subject to EPA recordkeeping requirements. EPA's Cost-Benefit Analysis estimates that there are about 1.2 million facilities subject to EPA's reporting requirements.[20] At least that many regulated facilities are subject to EPA's recordkeeping requirements. While there are indications of more than 1.2 million facilities being subject to EPA recordkeeping requirements,[21] even that number is sufficient to indicate that EPA greatly underestimated the number of regulated facilities that would be affected by the CROMERRR recordkeeping provisions.

3. The Costs of the Recordkeeping Provisions Would Be Prohibitive.

Using EPA's own cost estimates, the recordkeeping provisions would be extraordinarily expensive, and would have negative net benefits to regulated entities. Using more realistic cost estimates, the recordkeeping provisions would be astoundingly expensive, on the order of Y2K compliance costs.

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[17] EPA has acknowledged at least that "While the rule is voluntary because it does not require electronic reporting or recordkeeping, for most programs regulated entities that currently maintain electronic records and who wish to continue to do so after the rule takes effect would be required to meet the recordkeeping criteria in subpart D [sic – should be subpart C]. As currently defined in the proposal, the term electronic record is broad in scope." 67 Fed. Reg. at 279.

[18] 66 Fed. Reg. at 46178.

[19] CROMERRR ICR at 30. See also p. 33.

[20] Logistics Management Institute, "Cross-Media Electronic Reporting and Records Rule Cost-Benefit Analysis" (Mar. 2001), item II-A-039 in this docket ("Cost-Benefit Analysis"), at 3-3.

[21] For example, EPA's Fiscal Year 2000 Annual Report (Mar. 2001), available at www.epa.gov/ocfo/finstatement/2000ar/2000ar.htm, states at p. II-93, "In partnership with the states and federally recognized tribes, EPA's enforcement and compliance assurance program regulates approximately 8 million entities . . . . Compliance data are maintained for approximately 1.7 million of these entities."

a. EPA Estimates Yield Initial Costs of $48 Billion and Annual Costs of $20 Billion.

EPA's Cost-Benefit Analysis estimates the following costs per facility to implement the recordkeeping provisions:

> Our review of commercial systems shows that in the first year, a low-end but scalable [electronic recordkeeping system] costs approximately $25,000 plus an estimated additional $15,000 in internal labor for a training system and process set-up. We estimate annual maintenance of the software and managing the records at $17,000. These costs are very significant.[22]

> Most small- to medium-size organizations do not have automated electronic record-keeping systems that will meet CROMERRR requirements. Acquiring and implementing even low-end systems is likely to cost $40,000 or more. This cost is prohibitive for solely preserving environmental compliance reports. However, larger organizations that do have electronic record-keeping systems for other purposes most likely can expand the systems to accommodate electronic compliance reports at little added expense.[23]

A $40,000 up-front investment, when multiplied by at least 1.2 million affected regulated entities, yields an initial cost of at least $48 billion.

A $17,000 annual cost, when multiplied by at least 1.2 million affected regulated entities, yields an annual cost of at least $20 billion.

These figures are for "low-end" systems. They assume that larger entities will incur "little added expense" in meeting CROMERRR requirements.

By way of comparison, OSHA's ergonomics rule would have cost employers about $4.5 billion annually.[24] The initial cost of the CROMERRR recordkeeping provisions as estimated by EPA would have been more than ten times the annual cost of the ergonomics rule. The annual cost of the CROMERRR recordkeeping provisions as estimated by EPA would have been more than four times that of the ergonomics rule.

Congress passed legislation disapproving the ergonomics rule because of its excessive costs.[25] In signing that legislation, President Bush said, in words even more applicable to the CROMERRR recordkeeping requirements:

> There needs to be a balance between and an understanding of the costs and benefits associated with Federal regulations. In this instance, though, in exchange for uncertain benefits, the ergonomics rule would have cost both large and small

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[22] Cost-Benefit Analysis at 3-7.
[23] Cost-Benefit Analysis at 5-2.
[24] 65 Fed. Reg. 68262, 68779 (Nov. 14, 2000).
[25] Pub. L. No. 107-5, 115 Stat. 7.

> employers billions of dollars and presented employers with overwhelming compliance challenges. Also, the rule would have applied a bureaucratic one-size-fits-all solution to a broad range of employers and workers—not good government at work.[26]

EPA's own estimates found that the costs of the recordkeeping provisions would significantly exceed the benefits to regulated entities:

> The average annual cost to implement a new electronic record keeping system is $40,000 for each facility, and the net average annual cost savings for operating the electronic record keeping system is $23,000 . . . . Therefore, our estimates indicate that . . . facilities may not find it cost-effective to develop an electronic records system unless it addresses both EPA and non-EPA business purposes.[27]

> Most organizations probably will choose to . . . maintain paper records until technologies evolve that are simultaneously cost effective to implement and sufficiently secure as to meet enforcement and archiving requirements.[28]

> Electronic record keeping will require more research, application of technology, and coordination between enforcement requirements and workable solutions before it becomes cost effective for facilities.[29]

> EPA is continuing to research electronic record-keeping options that will improve the cost effectiveness of electronic record-keeping while meeting federal enforcement requirements.[30]

If CROMERRR's recordkeeping provisions were truly voluntary, then negative net benefits to regulated entities would be of relatively little moment, as regulated entities could choose not to take advantage of the option of electronic recordkeeping. As shown above, however, electronic recordkeeping is mandatory in practical effect. Accordingly, the problem of negative net benefits becomes tremendously important.

In summary, EPA's own estimates indicate that the CROMERRR recordkeeping provisions would be extraordinarily expensive and their costs would substantially exceed their benefits to regulated facilities.

b. Industry Cost Estimates Are Orders of Magnitude Higher.

Dow has submitted its analysis that the CROMERRR recordkeeping provisions would cost in excess of $1 million per facility.[31] Others, such as the American Petroleum Institute, have submitted cost estimates that are even higher.

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[26] 37 Weekly Compilation of Presidential Documents 477 (Mar. 20 2001).
[27] 66 Fed. Reg. at 46178.
[28] Cost-Benefit Analysis at 5-3.
[29] Cost-Benefit Analysis at 5-4.
[30] 66 Fed. Reg. at 46179.
[31] See Dow's written presentation submitted at the October 29, 2001 public hearing.

An analysis of the cost of FDA's counterpart to CROMERRR, 21 CFR Part 11, has found that costs for complying with Part 11 are exceedingly high. A leading pharmaceutical trade association reported to FDA:

> Although the Agency concluded that the Regulation will not have significant economic impact, PhRMA companies are estimating the financial impact to be **significantly higher than the cost of resolving any Y2K problems** . . . . In one case, **it cost $600,000 to bring a chromatography system into compliance.** There are hundreds of such systems that are bound by the Regulation. One large company has estimated that **archiving a complex electronic system would cost them in excess of ten million dollars** over the retention period. The cost to fully comply with the Regulation is expected to **exceed $150 million** for a large pharmaceutical company.[32]

> Experience gained by both FDA and the pharmaceutical industry . . . since the introduction of 21 CFR Part 11 in 1997 has shown that the cost and complexity of achieving compliance is significantly greater than was originally anticipated. The cost to a major pharmaceutical company is now understood to be in excess of $100M [million]. A number of key factors have contributed to this, including:
> 1. Companies have large numbers of systems covered by the rule. In the case of pharmaceutical companies, this can comprise several hundred systems.
> 2. The guidance provided by FDA has been ambiguous, leading to a variable approach to inspections and feedback.
> 3. Systems are strongly interconnected so that changes made to a given system have broad implications requiring extensive testing and validation.
> 4. Commercial software packages used in the industry often lack the functionality required by the regulation and it takes significant time for vendors to incorporate the required functionality into their products.
> 5. Some of the technologies required are new and immature and it can take several years for these to be incorporated into major commercial products.
> 6. The rapid pace of change of technology makes it difficult to provide secure long term archiving of data in electronic form.[33]

A group of affected pharmaceutical companies similarly told FDA:

> [T]he extensive experience that has now been gained from attempting to implement [Part 11] within the regulated industries has highlighted a number of difficulties giving rise to significant costs and risks that may outweigh the benefits

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[32] Pharmaceutical Research and Manufacturers of America, "21 CFR Part 11: A Partnership Approach to Achieving Regulatory Compliance for Electronic Records and Signatures" (Nov. 15, 1999) at 8 (emphasis added), available at www.fda.gov/ohrms/dockets/dailys/120899/c00004.pdf (Attachment 2).

[33] Pharmaceutical Research and Manufacturers of America, "Proposed FDA Guidance on the Scope and Implementation of 21 CFR Part 11" (Oct. 29, 2001) at 2-3, available at www.fda.gov/ohrms/dockets/dockets/00d1541/2.htm (Attachment 3).

> . . . . **Companies are investing millions of dollars in "good faith efforts" to comply with the Regulation.**[34]

A recent survey found costs totaling in excess of $100 million per company:

> Depending on the extent of legacy systems deployed, the impact of Part 11 could be **greater than the Y2k remediation effort**. Part 11 establishes new requirements for legacy systems that were not explicitly defined as essential for regulatory compliance.
>
> In a recent survey conducted by Accenture concerning leading companies' approaches to Part 11 compliance, respondents place the total cost to become compliant with 21 CFR Part 11 at **about $100+ million**, with additional time and money slated for maintenance.[35]

Why would the recordkeeping provisions be so costly? Because they would establish new requirements not previously defined as required for regulatory compliance. As a result, current (legacy) systems, and most systems now under development, lack the functionality that the recordkeeping provisions would require. Regulated facilities would have to purchase, validate, implement, and train on retrofitting solutions not designed for their systems, or purchase new systems, at a cost on a scale of the Y2K effort. That has been industry's experience with implementing Part 11:

> Compliance with the Regulation requires upgrading or replacing most current systems and, potentially, the introduction of new, and relatively unproved, technologies. Experience in the industry shows that change programs on this scale carry a significant degree of risk and expense . . . . Few companies would attempt to complete changes on this scale in less than 10-15 years. Attempting to accelerate this process would significantly increase the cost and level of risk.[36]

c. Audit Trail Costs Would Be a Large Component of the Costs.

The audit trail requirement would be particularly expensive. CROMERRR would require, among other things, that electronic records systems:

> Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records or documents.[37]

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[34] Industry Coalition on 21 CFR Part 11, "Recommendations for Achieving Compliance with the e-Records and e-Signatures Regulation" (Aug. 29, 2000) at 2-3 (emphasis added), available at www.fda.gov/ohrms/dockets/dockets/00d1539/00d1539.htm (Attachment 4).

[35] Accenture, "White paper: 21 CFR Part 11: Achieving business benefits" (2001) at 9 (emphasis added) (Attachment 5).

[36] Pharmaceutical Research and Manufacturers of America, "21 CFR Part 11: A Partnership Approach to Achieving Regulatory Compliance for Electronic Records and Signatures" (Nov. 30, 1999) at 9 (emphasis added), available at www.fda.gov/ohrms/dockets/dailys/121799/c009609.pdf (Attachment 2).

[37] Proposed 40 CFR 3.100(a)(6), 66 Fed. Reg. at 46190.

Virtually no software now in use generates such audit trails. Accordingly, virtually all software now used in connection with EPA recordkeeping requirements would need to be either replaced with software that does have an audit trail capability or supplemented with software which adds system-wide audit trail capability. The software licensing fees alone would be extremely expensive. Even more expensive would be the cost of integrating and validating such new software in the myriads of applications now in use.

An example is Microsoft Excel®. Excel is probably the leading software for presenting and processing data. Microsoft Corporation has not built into the software an audit trail capability, nor has it indicated any interest in doing so in the future. Accordingly, either every regulated facility that uses Excel in meeting EPA recordkeeping requirements would have to stop using Excel, and buy, validate, train on, and then use alternative software, or it would have to buy, validate, train on, and then use additional software that purports to add an audit trail capability for Excel.

Dow is aware of a single vendor that claims to have developed software (for stand-alone computers only, not for networked implementations) that will add an audit trail capability for Excel in order to help achieve compliance with 21 CFR Part 11.[38] Every user would have to test the software extensively to ensure that it works in its applications. The user would have to train its personnel on how to use the software. The user would have to pay the vendor for the use of the software. When multiplied by approximately 1.2 million users subject to EPA recordkeeping requirements, these costs are very significant. Notably, however, they would only address Excel. The hundreds of other kinds of software used in complying with EPA recordkeeping requirements would need their own solutions. For most of them, there is no website advertising a fix for a fee.

A related cost would be that of memory storage. Most software is written to minimize the amount of memory used by the application. The meta-data collected by an audit trail would multiply the system memory requirements by a substantial factor.

d. The Recordkeeping Provisions Would Put U.S. Laboratories at a Competitive Disadvantage.

A hidden cost of the audit trail requirement would be its impact on competition of U.S. and foreign laboratories subject to Good Laboratory Practice ("GLP") requirements. Outside the U.S., the leading set of GLP requirements is that of the Organization for Economic Co-operation and Development ("OECD"). While currently EPA and OECD GLP requirements are equivalent, allowing laboratories here and abroad to compete on an equal footing, CROMERRR would make the EPA GLPs much more expensive to meet, thus creating a competitive disadvantage for U.S. laboratories.

The OECD GLP requirements require audit trails, but not necessarily computer-generated audit trails:

[38] See FDA, "Memo of Meeting" (Mar. 7, 2001), available at www.fda.gov/ohrms/dockets/dockets/00d1541/00d1541.htm (Attachment 6).

> Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the person having made those changes, for example, by use of times and dated (electronic) signatures. Reasons for changes should be given.[39]

This language is comparable to that in EPA's GLP regulations also requiring an audit trail, but not necessarily a computer-generated one:

> In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.[40]

If CROMERRR were to require computer-generated audit trails, then U.S.-based laboratories subject to CROMERRR would incur the costs of acquiring computer-generated audit trails but those outside the U.S., following OECD GLP requirements, would not be. This would prove to be a significant competitive disadvantage.[41]

Similarly, both the OECD and EPA GLPs define the key term "raw data" to include copies in another medium. CROMERRR would disrupt the current ability to retain electronic records in another medium.

The OECD definition refers to:

> all original test facility records and documentation, or verified copies thereof . . . . Raw data also may include, for example, photographs, microfilm or microfiche copies . . . , or any other data storage medium that has been recognized as capable of providing secure storage of information for [the retention period].[42]

EPA's corresponding definition includes:

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[39] OECD, "OECD Principles on Good Laboratory Practice" (as revised in 1997), ENV/MC/CHEM(98)17 (referred to herein as "OECD GLPs"), available at http://www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-document-526-14-no-27-6553-526,FF.html (Attachment 7), § 8.3.5.

[40] 40 CFR §§ 160.130(e), 792.130(e).

[41] Part 11 requires computer-generated audit trails. 21 CFR § 11.10(e). FDA originally proposed for Part 11 an audit trail requirement without specifying that it had to be computer-generated. Proposed 21 CFR § 11.10(e), 59 Fed. Reg. 45160 (Aug. 31, 1994). According to the preamble to the final rule, "Several comments [in response to the proposed rule] focused on the question of whether audit trails should be generated manually under operator control or automatically without operator control." FDA concluded that the audit trail should be computer-generated. 62 Fed. Reg. at 13447.

[42] OECD GLPs, § 2.3.7.

> any laboratory worksheets, records, memoranda, notes, or exact copies thereof .... "Raw data" may include photographs, microfilm or microfiche copies, computer printouts ....[43]

The proposed CROMERRR requirement to retain electronic records electronically for the entire retention period[44] would take away the flexibility of U.S. laboratories to keep electronic records in another medium that is cheaper to maintain over long periods, creating another competitive disadvantage.

e. The Searchability Requirement Would Also Add Costs.

Another significant cost element of the recordkeeping provisions is the proposed requirement that electronic records be searchable:

> Ensure that electronic records and electronic records are searchable and retrievable for reference and secondary uses, including inspections, audits, legal proceedings, third party disclosures, as required by applicable regulations, for the entirety of the required period of record retention.[45]

The preamble does not explain this searchability requirement, which is not explicitly stated in FDA's Part 11.

Nevertheless, FDA has by interpretation found a searchability requirement in Part 11's requirement that covered entities be able to generate electronic copies of records "suitable for inspection, review, and copying by the agency",[46] as shown by the following FDA statements:

> We [FDA] commented that to be suitable for our use electronic copies need to be in a format that permits us to process (e.g., search and sort) information. Thus, a PDF file of a table or spreadsheet would not meet this need, although a word searchable text file may meet this requirement.[47]

> During the course of the meeting we [FDA] commented that PDF file formats that did not permit the processing of record information would be problematic. We noted that for records containing only text, there should be no problem with a PDF file that permitted word searches; however, we remarked that information in the files that could not be processed, such as images of spreadsheets and tables would be problematic from a part 11 perspective. Part 11 requires that persons be

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[43] 40 CFR §§ 160.3, 792.3.
[44] Proposed 40 CFR § 3.100(a)(2), 66 Fed. Reg. at 46190.
[45] Proposed 40 CFR § 3.100(a)(8), 66 Fed. Reg. at 46190.
[46] 21 CFR § 11.10(b).
[47] FDA, "Memo of Meeting" (June 14, 2001), available at www.fda.gov/ohrms/dockets/dockets/00d1538/mm00012.pdf (Attachment 8).

> able to generate electronic copies of electronic records that are suitable for FDA review.[48]
>
> Moreover, a major principle in part 11 is that for FDA to be able to protect and promote public health it must function on the same technological plane as the regulated industry. We couldn't do that if firms were allowed to destroy their electronic records and present to FDA investigators only paper archives because investigators would not be able to apply information technology based tools such as search and sort techniques when reviewing those records.[49]

It is likely that EPA had intended to incorporate explicitly FDA's implicit requirement that electronic records be searchable.

As indicated by the first two quotations above, a searchability requirement limits the technological options available to regulated entities. This necessarily means that some archiving options, such as PDF files, would not be acceptable for CROMERRR compliance, even though they would be electronic records. Limiting available technological options raises costs to regulated entities.

4. The Electronic Archiving Requirement Would Be Technologically Infeasible.

Another aspect of the CROMERRR recordkeeping provisions, the requirement for electronic archiving, is not just costly; it is unachievable.

The proposed requirement reads:

> Maintain all electronic records and electronic documents without alteration for the entirety of the required period of record retention.[50]

The preamble explains this proposed requirement:

> Depending on the record retention period required in predicate regulations, regulated entities must insure that the complete records, including the related metadata, can be maintained in secure and accessible form on the preexisting system or migrated to a new system, as needed, throughout the required retention period.[51]

This requirement would be infeasible, as explained below.

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[48] FDA, "Memo of Meeting" (Aug. 9, 2001), available at www.fda.gov/ohrms/dockets/dockets/00d1539/mm00016.pdf (Attachment 9).
[49] FDA, "Human Drug CGMP Notes", Vol. 6, No. 3 (Sept. 1998), available at www.fda.gov/cder/hdn/cnotes98.pdf (Attachment 10).
[50] Proposed 40 CFR § 3.100(a)(2), 66 Fed. Reg. at 46190.
[51] 66 Fed. Reg. at 46170. Similarly, the FDA preamble to Part 11 said, "persons would not necessarily have to retain supplanted hardware and software systems provided they implemented conversion capabilities when switching to replacement technologies." 62 Fed. Reg. at 13446 (comment 71).

a. Retention Periods May Last for Decades.

First, the archiving period would extend well beyond the current life of affected software and hardware. Under EPA recordkeeping regulations, in some cases the record retention period is for a few years, but with others it can last decades. For example:

- Under the EPA FIFRA GLP regulations, GLP data relating to a study submitted to support a pesticide registration must be maintained for "the period during which the sponsor holds any research or marketing permit to which the study is pertinent", i.e., for the life of the registration.[52]
- Under the EPA boiler and industrial furnace ("BIF") regulations, the owner or operator of a BIF "must keep in the operating record of the facility all information and data required by this section until closure of the facility."[53]

b. The Technical Problems Are Unsolved.

In many cases it may not be technically feasible to meet the CROMERRR archiving requirement. In others the cost may be economically infeasible. Some of the reasons are explained in a *Scientific American* article[54] cited by the Justice Department in a guide to federal agencies on implementing electronic processes.[55]

The article first explains in laymen's terms that digital documents are essentially programs in need of software to read them:

> Digital information can be saved on any medium that is able to represent the binary digits ("bits)" 0 and 1. We will call an intended, meaningful sequence of bits, with no intervening spaces, punctuation, or formatting, a bit stream . . . .
>
> [I]nterpreting a bit stream depends on understanding its implicit structure, which cannot be explicitly represented in the stream. A bit stream that represents a sequence of alphabetical characters may consist of fixed-length chunks ("bytes"), each representing a code for a single character . . . . To extract the bytes from the bit stream, thereby "parsing" the stream into its components, we must know the length of a byte . . . .
>
> Most files contain information that is meaningful solely to the software that created them . . . . For convenience, we call such embedded information—and all other aspects of a bit stream's representation, including byte length, character code and structure—the encoding of a document file. These files are essentially

[52] 40 CFR § 160.195(b)(1).
[53] 40 CFR § 266.102(e)(10). EPA has proposed to shorten this retention period to three years. Proposed 40 CFR § 266.102(e)(10), 67 Fed. Reg. 2518, 2529 (Jan. 17, 2002).
[54] Jeff Rothenberg, "Ensuring the Longevity of Digital Documents", *Scientific American*, Vol. 272, No. 1 (Jan. 1995), pp. 42-47 (Attachment 11).
[55] See U.S. Department of Justice, "Legal Considerations in Designing and Implementing Electronic Processes: A Guide for Federal Agencies" (Nov. 2000), n. 10, available at www.cybercrime.gov/eprocess.pdf (Attachment 12).

> programs: instructions and data that can be interpreted only by appropriate software. A file is not a document in its own right—it merely describes a document that comes into existence when the file is interpreted by the program that produced it. Without this program (or equivalent software), the document is a cryptic hostage of its own encoding . . . .

As EPA identified, the only options are maintaining legacy systems or migrating the data. The article identifies "serious shortcomings" with the idea of maintaining legacy systems, related to both software and hardware:

> [To read old digital documents,] we must save the programs that generate our digital documents, as well as all the system software required to run those programs. Although this task is monumental, it is theoretically feasible.

Preserving software is not sufficient, however; hardware must also be preserved:

> How can we provide the hardware to run antiquated systems and application software? A number of specialized museums and "retro-computing" clubs are attempting to maintain computers in working condition after they become obsolete. Despite a certain undeniable charm born of its technological bravado, this method is ultimately futile. The cost of repairing or replacing worn out components (and retaining the expertise to do so) must inevitably outweigh the demand for any outmoded computer.

Next, the article addresses the problems with migrating, or "translating", data as software changes:

> Is it necessary to run the specific program that created a document? In some cases, similar software may at least partially be able to interpret the file. Still, it is naive to think that the encoding of any document—however natural it may seem to us—will remain readable by future software for very long. Information technology continually creates new schemes, which often abandon their predecessors instead of subsuming them . . . .
>
> Translating a document into successive short-term standards offers false hope. Successive translation avoids the need for ultimate standards [which are not available now], but each translation introduces new losses . . . .
>
> Finally, translation suffers from a fatal flaw. Unlike English and ancient Greek, whose expressive power and semantics are roughly equivalent, digital documents are evolving so rapidly that shifts in the forms of documents must inevitably arise. New forms do not necessarily subsume their predecessors or provide compatibility with previous formats. Old documents cannot always be translated into unprecedented forms in meaningful ways, and translating a current file back into a previous form is often impossible. For example, many older, hierarchical databases were completely redesigned to fit the relational model, just as relational

databases are now being restructured to fit emerging object-oriented models. Shifts of this kind make it difficult or meaningless to translate old documents into new standard forms.

If digital documents and their programs are to be saved, their migration must not modify their bit streams, because programs and their files can be corrupted by the slightest change . . . Although bit streams can be designed to be immune from any expected change, future migration may introduce unexpected alterations. For example, aggressive data compression may convert a bit stream into an approximation of itself, precluding a precise reconstruction of the original. Similarly, encryption makes it impossible to recover an original bit stream without the decryption key.

The bottom line is that CROMERRR's proposed archiving requirement, maintaining digital documents "without alteration", potentially for decades, is currently technologically infeasible.

c. The Federal Government Has Been Unable to Find a Solution.

The federal government itself has been wrestling with the problem of how to archive electronic records without data loss, and has been unable to come up with a solution. EPA cannot reasonably expect the 1.2 million or more regulated entities to comply with the proposed archiving requirement when the federal government has been unable to do so after spending millions of dollars trying.

A recent report for the National Archives and Records Administration ("NARA") describes the current state of affairs:

> **Government employees do not know how to solve the problem of electronic records – whether the electronic information they create constitutes records and, if so, what to do with the records.** Electronic files that qualify as records—particularly in the form of e-mail, and also word processing and spreadsheet documents—are not being kept at all as records in many cases and are frequently not being scheduled. Employees lack guidance and knowledge concerning how to identify electronic records and what to do with them once identified. Technology tools for managing electronic records do not exist in most agencies. The agency information technology environments have not been designed to facilitate the retention and retrieval of electronic records. Despite the growth of electronic media, agency records systems are predominately in paper format rather than electronic. Virtually every agency visited indicated that the official policy is that their records will be maintained in paper format. Yet the agencies recognize that most records are now created in an electronic environment—in word-processing documents, spreadsheets, databases, and the like. The predominate e-mail policy is to print out e-mails that are considered records and to save the paper copies.

> The chief paradox of today's Federal RM [records management] is the disconnect between paper and electronic recordkeeping.[56]

NARA itself has recognized the technological challenges:

> Because long-term temporary and permanent electronically signed records have greater longevity than typical software obsolescence cycles, it is virtually certain that agencies will have to migrate those records to newer versions of software to maintain access. The software migration (as opposed to media migration) process may invalidate the digital signature embedded in the record. This may adversely affect an agency's ability to recognize or enforce the legal rights documented in those records.[57]

The Government Accounting Office has referred to this problem:

> The long-term preservation and retention of those electronic records is also a challenge since providing continued access to archived records over many generations of systems is difficult. The average life of a typical software product is 2 to 5 years.[58]

So has the Justice Department:

> Agencies should consider several factors related to the accessibility of electronic records. First, computer technology is rapidly changing and software and formatting standards may quickly become obsolete. Computer-stored data may become useless unless the agency can provide the continued capability with the older technologies or can accurately translate the document as more modern systems are implemented. Second, if in the future, an agency no longer has staff who are familiar and competent to work with the electronic processes necessary to read older data, such data could be functionally unavailable. Electronic files might be stored while encrypted by software or protected by passwords no longer available or remembered years later, unless steps are taken to preserve the software or passwords.[59]

In summary, the federal government itself is not archiving electronic records electronically, nor has it solved the problem of how to do so for extended periods without

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[56] SRA International, Inc., "Report on Current Recordkeeping Practices within the Federal Government, Prepared for the National Archives and Records Administration" (Dec. 10, 2001), available at www.nara.gov/records/rmi.html (Attachment 13) at 5-6 (emphasis in original).

[57] NARA, "Records Management Guidance for Agencies Implementing Electronic Signature Technologies" (Oct. 18, 2000), available at www.nara.gov/records/policy/gpea.html (Attachment 14), § 5.5 (emphasis in original).

[58] Government Accounting Office, "National Archives: Preserving Electronic Records in an Era of Rapidly Changing Technology", GAO/GGD-99-94 (July 1999), available at www.gao.gov/archive/1999/gg99094.pdf (Attachment 15).

[59] Department of Justice, "Legal Considerations in Designing and Implementing Electronic Processes: A Guide for Federal Agencies" (Nov. 2000), available at www.cybercrime.gov/eprocess.htm (Attachment 12), § II.A.3 (footnote omitted).

data loss. What the federal government has been unable to achieve is an inappropriate requirement for EPA to impose on over 1.2 million regulated facilities.

5. The Recordkeeping Provisions Are Not Supported by the Government Paperwork Elimination Act.

EPA cannot rely on the Government Paperwork Elimination Act ("GPEA")[60] to justify the CROMERRR recordkeeping provisions. The GPEA does not require EPA to take any action with respect to recordkeeping other than to remove obstacles to electronic recordkeeping.

According to the preamble,

> EPA is proposing this rule on cross-media electronic reporting and record-keeping, in part, under the authority of the [GPEA], which amends the PRA [Paperwork Reduction Act].[61]

Section 1704 of the GPEA directs OMB to

> ensure that, [by October 2003], Executive agencies provide—
> (1) for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and
> (2) for the use and acceptance of electronic signatures, when practicable.

In other words, EPA has an obligation to provide regulated entities with an option of electronic recordkeeping. There is no EPA obligation to protect against fraud.

EPA already allows electronic recordkeeping. For example, the general recordkeeping provision of the NESHAPs regulations under the Clean Air Act provides:

> **Such files may be maintained** on microfilm, **on a computer**, on computer floppy disks, on magnetic tape disks, or on microfiche.[62]

EPA has many other regulations explicitly authorizing electronic recordkeeping.[63]

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[60] Title XVII of Division C of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 15-277, 112 Stat. 2681-749 to –751.
[61] 66 Fed. Reg. at 46185.
[62] 40 CFR § 63.10(b)(1) (emphasis added).
[63] See, e.g., 40 CFR § 60.58c(f); 40 CFR § 60.59a(b)(2)(i); 40 CFR § 60.59b(k); 40 CFR § 60.2180; 40 CFR § 60.2745; 40 CFR § 62.14462; 40 CFR § 63.103(c)(1); 40 CFR § 63.104(c)(3); 40 CFR § 63.152(g)(1)(vi)(D); 40 CFR § 63.181(a); 40 CFR § 63.192(f)(1); 40 CFR § 63.506(a)(1); 40 CFR § 63.642(e) 40 CFR § 63.774(b)(1)(ii); 40 CFR § 63.850(e)(2); 40 CFR § 63.998(b)(5)(i)(F)(*4*); 40 CFR § 63.1065; 40 CFR § 63.1109(c); 40 CFR § 63.11.92(d); 40 CFR § 63.1255(g)(1); 40 CFR § 63.1284(b)(1)(iv); 40 CFR § 63.1335(a)(1); 40 CFR § 63.1355(a); 40 CFR § 63.1363(g)(1); 40 CFR § 63.1386(d)(1)(ii); 40 CFR § 63.1409(c)(3); 40 CFR § 63.1416(a)(1); 40 CFR § 63.1439(a); 40 CFR § 63.1517(a)(2); 40 CFR § 63.5770(d); 40 CFR § 64.9(b)(2); 40 CFR § 65.4(c)(3); 40 CFR § 65.161(e)(1)(vi)(D); 40 CFR § 85.1806(e); 40 CFR § 85.1904(d).

Other EPA regulations are media-neutral as to how required records must be kept, and thus they implicitly authorize electronic recordkeeping. Some are silent on how records are to be kept, while others explicitly allow any accurate format. For example, EPA's GLP regulations provide:

> Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.[64]

Accordingly, EPA has already authorized electronic recordkeeping, either explicitly or implicitly. Only if an EPA recordkeeping requirement somehow required paper (e.g., by referring to a handwritten signature) would any action by EPA be necessary to meet the GPEA requirement to enable regulated entities to keep records electronically.

It should be noted that although the GPEA applies to all federal agencies, very few have proposed or adopted rules implementing the GPEA. Most apparently consider that guidance authorizing the use of electronic reporting, electronic signatures, and electronic recordkeeping is sufficient.

6. The Recordkeeping Provisions Would Contravene the GPEA.

Far from being necessary for GPEA compliance, the CROMERRR recordkeeping provisions would actually contravene the GPEA, for several reasons.

a. They Would Treat Electronic Records Less Favorably Than Paper Records.

First, the GPEA is intended to prohibit discrimination against electronic recordkeeping, and CROMERRR would do exactly that. Section 1707 of the GPEA provides:

> Electronic records submitted or maintained in accordance with procedures developed under this title,[65] or electronic signatures or other forms of electronic authentication used in accordance with such procedures, shall not be denied legal effect, validity, or enforceability because such records are in electronic form.

The legislative history of this wording explains:

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[64] 40 CFR §§ 160.195(i), 792.195(i).

[65] The "title" referred to is Title XVII of Division C of the Omnibus Consolidated Appropriations Act, 1999, i.e., the GPEA. The phrase "procedures developed under this title" refers to OMB's "procedures for the use and acceptance of electronic signatures by Executive agencies", see Section 1703(a) of the GPEA. See also Section 1703(b): "REQUIREMENTS FOR PROCEDURES.—(1) The procedures developed under subsection (a) . . . ." Thus, the "procedures" referred to in Section 1707 relate solely to electronic signatures, and not to electronic recordkeeping generally.

> This provision is intended to preclude agencies or courts from systematically treating electronic documents and signatures less favorably than their paper counterparts.[66]

Yet the CROMERRR preamble clearly states EPA's intention to "improve" the accountability of electronic records over that of paper records:

> In proposing to allow regulated entities to submit electronic documents and maintain electronic records, EPA has at least, the following three goals: . . .
> - To maintain **or improve** the level of corporate and individual responsibility and accountability for electronic reports and records that currently exists in the paper environment.[67]

Thus, EPA proposes to burden electronic recordkeeping with additional anti-fraud safeguards beyond the equivalent safeguards for paper, such as audit trails and searchability functionality. This is discrimination against electronic recordkeeping, contrary to the requirements of the GPEA.

The impact of this discrimination is obvious—EPA would make electronic recordkeeping tremendously expensive. As noted above,[68] EPA's own Cost-Benefit Analysis showed that only 428 regulated facilities per year would choose to undertake electronic recordkeeping as proposed by CROMERRR, because the costs would exceed the benefits. This is EPA's own admission that the recordkeeping provisions would systematically treat electronic records less favorably than their paper counterparts.

b. <u>They Would Increase Rather Than Decrease Paperwork Burdens.</u>

The GPEA amends the Paperwork Reduction Act, among whose purposes is to:

> minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, Federal contractors, State, local and tribal governments, and other persons resulting from the collection of information by or for the Federal Government.[69]

The GPEA legislative history emphasizes that:

> This legislation will not increase the paperwork requirement for private individuals or businesses.[70]

Yet EPA itself admits that for regulated facilities, the added costs of the recordkeeping provisions would significantly exceed the benefits.[71] In other words, the recordkeeping

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[66] S. Comm. on Commerce, Science, and Transportation, "Government Paperwork Elimination Act", S. Rep. No. 335, 105th Cong., 2nd Sess. (1998) ("Senate Report") at 7 (Attachment 16).
[67] 66 Fed. Reg. at 46166 (emphasis added).
[68] See § 3.a of these comments.
[69] 44 USC § 3501(1).
[70] Senate Report at 5.

provisions would actually increase paperwork costs, directly contrary to the purposes of both the GPEA and the Paperwork Reduction Act.

c. They Would Subject Regulated Facilities to Additional Regulation.

The GPEA did not contemplate that federal agencies would impose extensive anti-fraud requirements in making electronic recordkeeping available, as CROMERRR proposes to do. The legislative history is clear in stating:

> The Committee believes that the bill will not subject any individuals or businesses affected by the bill to any additional regulation.[72]

Undeniably, the CROMERRR recordkeeping provisions would subject all regulated facilities to additional regulation. The provisions include extensive requirements for audit trails, searchability functionality, archiving in electronic format, etc. These additional requirements are contrary to the intent of the GPEA.

Thus, it is ironic that EPA sought to justify CROMERRR's recordkeeping provisions by citing the GPEA. The GPEA does not require EPA to take anything like the actions proposed here, and it actually prohibits EPA from imposing requirements such as the recordkeeping provisions.

7. EPA Has Not Justified the Need for Anti-Fraud Provisions.

Since citation to the GPEA cannot justify the recordkeeping provisions, EPA must rely on its other stated objective, to "help minimize fraud" in electronic recordkeeping:

> For both document submission and record-keeping, the point of the proposed requirements is primarily to ensure that the authenticity and integrity of these documents and records are preserved as they are created, submitted, and/or maintained electronically, so that they continue to provide strong evidence of what was intended by the individuals who created and/or signed and certified them. Among other things, today's proposal is intended to ensure that the federal laws regarding the falsification of information submitted to the government still apply to any and all electronic transactions; and that fraudulent electronic submissions or record-keeping can be prosecuted to the fullest extent of the law. In establishing clear requirements for electronic reporting systems and electronic records, this proposed rule will help minimize fraud by assuring that the responsible individuals can be readily identified.[73]

But EPA has failed to justify why such stringent anti-fraud provisions as appear in the recordkeeping provisions are needed. There is nothing in this docket to support EPA's

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[71] See the discussion at § 3.a of these comments.
[72] Senate Report at 5.
[73] 66 Fed. Reg. at 46164.

implicit claim that fraud in electronic recordkeeping is a significant problem throughout EPA programs or that the proposed anti-fraud provisions are appropriate.

a. EPA Did Not Conduct Required Analyses.

Most notably, EPA has failed to follow OMB's directions to federal agencies in implementing the GPEA to conduct a risk assessment for fraud in electronic recordkeeping, and a separate cost-benefit analysis of provisions aimed at curbing such fraud:

> Accordingly, agencies should develop and implement plans, supported by an assessment of whether to use and accept documents in electronic form and to engage in electronic transactions. The assessment should weigh costs and benefits and involve an appropriate risk analysis, recognizing that low-risk information processes may need only minimal consideration, while high-risk processes may need extensive analysis.[74]

Similarly, the Justice Department has advised federal agencies considering electronic reporting and recordkeeping to:

> 1. Conduct an analysis of the nature of a transaction or process to determine the level of protection needed and the level of risk that can be tolerated . . . .
> 2. Consider potential costs and benefits, quantifiable and unquantifiable, direct and indirect, in performing a cost/benefit analysis.[75]

OEI staffers have admitted that any such analysis performed by EPA with respect to CROMERRR failed to address the recordkeeping provisions. No such risk analysis or cost-benefit analysis appears in the public docket.

The reason for these required analyses was to cause agencies to refrain from overreacting to the prospect of fraud in electronic records:

> Setting up a very secure, but expensive, automated system may in fact buy only a marginal benefit of deterrence or risk reduction over other alternatives and may not be worth the extra cost. For example, **past experience with fraud risks, and a careful analysis of those risks, shows that exposure is often low.** If this is the case a less expensive system that substantially deters fraud is warranted, and not an absolutely secure system. Overall, security determination should conform with the Computer Security Act: the level of security should be commensurate with the level of sensitivity of the transaction.[76]

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[74] 65 Fed. Reg. 25508, 25512 (May 2, 2000).

[75] Department of Justice, "Legal Considerations in Designing and Implementing Electronic Processes: A Guide for Federal Agencies" (Nov. 2000), available at www.cybercrime.gov/eprocess.htm (Attachment 12), § III.B.

[76] 65 Fed. Reg. at 25515 (emphasis added).

Following FDA's example, EPA apparently assumed that all EPA-mandated records, regardless of their nature, have the highest level of sensitivity. The OMB guidance cautions against this "one size fits all" approach:

> Agencies should also keep in mind that GPEA specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form. **We are not, therefore, prescribing "one size fits all" requirements applicable to transactions regardless of sensitivity.**[77]

In particular, the OMB guidance advises that the risk of fraud is lowest where there is an ongoing relationship, as with EPA and regulated entities:

> Risks tend to be relatively low in cases where there is an ongoing relationship between the parties. Generally speaking . . . , **transactions between a regulatory agency and a publicly traded corporation or other known entity regulated by that agency can often bear a relatively low risk of repudiation or fraud**, particularly where the regulatory agency has an ongoing relationship with, and enforcement authority over, the entity.[78]

EPA keeps careful track of its regulated entities, routinely inspects them, and deals with them on an ongoing basis. Accordingly, the risk of fraud is probably quite low.

In contrast to EPA and FDA, other federal agencies implementing the GPEA have chosen to adjust the degree of anti-fraud protections to the risk of fraud and the consequences of fraud. For example, the Treasury Department has adopted policies and practices for the use of electronic transactions and authentication techniques in federal payments and collections.[79] It uses a risk-based approach:

> All payment, collection, and collateral transactions must be properly authenticated, in a manner commensurate with the risks of the transaction.[80]

Transactions with negligible risk may occur without any electronic authentication technique. Those with low risk must use a single factor authentication, such as a personal identification number. Those with moderate or high risk would require more in the way of authentication, such as cryptography.

b. Lab Fraud Cases Do Not Support the Anti-Fraud Provisions.

OEI staffers have indicated that cases of alleged fraud by some independent laboratories justify the anti-fraud provisions.[81] This assertion is unsupported, for several reasons.

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[77] 65 Fed. Reg. at 25510 (emphasis added). Note also President Bush's condemnation of "one-size-fits-all" regulations in signing the legislation disapproving OSHA's ergonomics rule.
[78] 65 Fed. Reg. at 25517 (emphasis added).
[79] 66 Fed. Reg. 394 (Jan. 3, 2001).
[80] 66 Fed. Reg. at 396.
[81] See comments by David Schwarz in the transcript of the January 17 public meeting.

First, there is nothing in the record of this proceeding giving any information about lab fraud cases involving electronic recordkeeping. EPA has done nothing to provide evidence of lab fraud cases or their possible involvement of electronic recordkeeping.

Second, any lab fraud cases reported by EPA would be examples of enforcement successes that occurred without CROMERRR's anti-fraud provisions. Thus, those cases would tend to show that EPA can detect and prove fraud without the aid of CROMERRR, even in the laboratory.

Third, there is nothing in the record to indicate that fraud in electronic recordkeeping is a problem outside the laboratory context. Even if lab fraud were a substantial electronic recordkeeping problem, that would have no bearing on whether there is a need for anti-fraud provisions outside the laboratory setting.

Finally, EPA has other ways to deal with lab fraud without imposing the burdens of CROMERRR. EPA has shown in its GLP regulations that it knows how to address the potential for fraud in the laboratory context.

c. EPA's Determination That the Anti-Fraud Provisions Are Necessary to Ensure Reliability Conflicts With Judicial Experience Accepting Electronic Records as Reliable Evidence.

The preamble describes the anti-fraud provisions as crucial to establishing that electronic records are reliable:

> Today's proposal sets forth the criteria under which the Agency considers electronic records to be trustworthy, reliable, and generally equivalent to paper records in satisfying regulatory requirements.[82]

This position is inconsistent with the many civil and criminal cases in which electronic records have been admitted into evidence as reliable records. Electronic records (or printouts thereof) have been held admissible as reliable evidence for decades in both civil and criminal cases. Indeed, the Federal Rules of Evidence specifically facilitate the admission of electronic records. Rule 1001(4) provides that in the case of electronic records the requirement for an original record may be met by a printout. Rule 803(6), the "business records" exception to the hearsay rule, covers a "data compilation, in any form" (i.e., including electronic records). Any residual evidentiary concerns about electronic records are reduced by the GPEA, which provides that:

> Electronic records . . . maintained in accordance with procedures developed under this title [as noted previously, that language pertains to electronic signatures] . . . shall not be denied legal effect, validity, or enforceability because such records are in electronic form.[83]

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[82] 66 Fed. Reg. at 46166.
[83] GPEA, § 1707.

provisions would not be voluntary in a meaningful sense, and thus the preamble misrepresented the nature of the proposed rule.

b. The Paperwork Reduction Act.

Under the Paperwork Reduction Act, EPA must provide OMB with "a specific, objectively supported estimate of burden" for the collection of information and the control of paperwork.[88] While the CROMERRR ICR met the form of such an estimate, its burden estimate was not "objectively supported". As discussed above,[89] the CROMERRR ICR estimated that 428 regulated facilities per year would choose to subject themselves to the recordkeeping provisions, at an initial cost of $40,000 and an annual cost of $17,000.[90] The number of affected facilities is orders of magnitudes off, as are the cost estimates. EPA has not presented a realistic estimate of paperwork burden to OMB as required by the Paperwork Reduction Act.

c. The Regulatory Flexibility Act.

Under the Regulatory Flexibility Act, EPA must prepare an initial regulatory flexibility analysis discussing the impact of the proposed rule on small businesses, unless EPA makes a finding that the proposal will have no significant impact on small businesses.[91] In this case, EPA made such a determination:

> Today's rule is not subject to the RFA because electronic reporting and recordkeeping is voluntary . . . . These changes will reduce the burden on small businesses. Accordingly, this rule is certified as having no Significant economic impact on a substantial number of small businesses.[92]

As shown above,[93] the recordkeeping provisions would not be voluntary in any meaningful way and would have a tremendous economic impact on small businesses. Accordingly, EPA improperly determined that the Regulatory Flexibility Act does not apply. It must prepare a regulatory flexibility analysis.

d. The Unfunded Mandates Reform Act.

Under the Unfunded Mandates Reform Act of 1995, EPA must prepare a written statement containing an assessment of the anticipated costs and benefits of the proposed rule on the private sector or various governmental entities where the impact may exceed $100 million in a calendar year.[94] EPA did not prepare this analysis, instead stating:

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[88] 44 USC § 3506(c)(1)(A)((iv).
[89] See §§ 2, 3.a of these comments.
[90] See § 3b of these comments.
[91] 5 USC § 603.
[92] 66 Fed. Reg. at 46186.
[93] See §§ 2, 3.b of these comments.
[94] 2 USC § 1532(a).

> The Agency has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and tribal governments, or the private sector in any one year.[95]

As shown above,[96] the impact of CROMERRR on the private sector alone would involve initial costs of over $48 billion, many times the threshold for triggering the need to conduct an analysis. EPA still needs to complete that analysis.

10. EPA Should Withdraw the Recordkeeping Provisions Prior to Revising Them.

EPA should not attempt to revise the recordkeeping provisions in an effort to promulgate a final rule in the near term. Rather, it should withdraw them, subject them or alternatives to appropriate analysis, confer informally with affected regulated facilities, and only then, if appropriate, re-propose them.

As an initial matter, it should be clear that the GPEA does not impose a deadline on EPA to promulgate recordkeeping provisions. EPA already allows electronic recordkeeping. It needs to take no action to allow electronic recordkeeping to continue.[97]

To make the kinds of changes necessary to make anti-fraud provisions for electronic recordkeeping cost-effective, EPA must make fundamental changes to the proposal. To meet the Administrative Procedure Act's requirement to provide notice and opportunity for comment, EPA would have to propose those changes in the Federal Register; it could not simply promulgate them.

EPA needs to perform the kinds of analyses required by OMB and suggested by the Justice Department to determine the nature and extent of the risk of fraud in electronic recordkeeping in various program areas, and the costs and benefits of alternative measures to control that risk.[98] It needs to design an approach in which one size does not fit all. It needs to address actual risks of fraud where they exist in a measured way appropriate for the magnitude of that risk.

EPA also needs to perform the kinds of impact analyses required by the Paperwork Reduction Act, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act.[99]

EPA needs to consult with affected parties. While EPA held public meetings on CROMERRR prior to its official proposal, those meetings were heavily focused on electronic reporting and electronic signatures. As recently as August 2001, EPA had no idea that electronic recordkeeping is both pervasive in the regulated community and

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[95] 66 Fed. Reg. at 46186.
[96] See §§ 3.a, 3.b of these comments.
[97] See § 5 of these comments.
[98] See § 7.a of these comments.
[99] See § 9 of these comments.

critical to achieving compliance with EPA recordkeeping requirements. Next time, EPA should consult with regulated facilities in advance about the impact, costs, and benefits of various alternatives, including the alternative of taking no action.

CONCLUSION

EPA should withdraw the recordkeeping provisions. It should not attempt to promulgate either them or a revision without going through the full rulemaking process again.